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Applicants:	Dean, Herbert M. et al.
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Commissioner for Patents
Washington, D.C. 20231

DECLARATION OF DR. HERBERT M. DEAN

I, Dr. Herbert M. Dean, hereby declare the following:

1. I am recently retired but currently hold a part-time position as Medical Director of Verax Biomedical since 2000. Before retirement, I served as President of Fallon Community Health Plan for 8 years, as Treasurer of Fallon Community Health Plan for 3 years, and in various other capacities with Fallon Community Health Plan from its inception in 1977 to 1998. I am board certified in hematology, oncology and internal medicine and worked for Fallon Clinic, Inc. for 31 years. I also served on various committees at St. Vincent Hospital. My curriculum vitae is attached (Exhibit A).

2. In my many years with the Fallon Clinic and the Fallon Community Health Plan, my efforts in directing the health plan focused on the role of both primary preventive care as well as optimal management of members with cardiovascular disease. The goals were improved health of plan members and cost savings to the health care system.

3. Quality care ultimately costs less if successful interventions are done upstream rather than waiting for the development of disease.

4. Numerous studies have shown the benefit of using beta-blockers in patients who have had heart attacks, anginal symptoms, or are at high risk.

5. Similar, multiple, well-controlled medical reports have be n provided by numerous cardiac studies on the benefit of lowering serum cholesterol in patients with

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established cardiac disease as well as reducing heart attacks in those at increased risk.

6.　There are also other studies that address the concern that beta-blockers and lipid lowering medications are underutilized despite the positive findings of studies examining the effectiveness of these therapies and the widespread dissemination of practice guidelines.　(See Exhibit B and C)

7.　Individuals with cardiovascular disorders are known to commonly utilize many medications.　Older individuals are in the typical age group in which these cardio-preventative medications are required.　The inconvenience of taking multiple dosage units of many medications over a long period of time tends to decrease patient compliance.　Older patients are more susceptible to confusing their multiple medications and multiple treatment regimens.

8.　From my work experience with guiding and directing a health plan provider, health plan providers are continuously striving to improve the health of plan members as there is a correlation between quality healthcare and cost savings if medical interventions are done before the development of disease rather than waiting until after the disease develops.

9.　There is a need in the field for cardiovascular preventive treatment and to improve upon the failure of patients to avail themselves of such treatments.

10.　Despite the industry's many years of knowledge of the benefits of using beta-blockers, of lowering serum cholesterol in patients with established cardiac disease, and of the knowledge of compliance problems related to long-term treatments with multiple medications especially in older patients, no treatment protocols or regimens have proposed, discussed or suggesed using a single dose, multiple-medication containing dosage unit for cardiovascular preventative treatment.　Their answer to these problems are to educate physicians and patients.

11.　There is no such device presently available to caregivers or patients to facilitate treatment, increase convenience, reduce cost, and enhance compliance where long-term treatments are required.

12. The single dose, beta-blocker and cholesterol-lowering agent described in the present application would be a clear improvement over the current state of cardiovascular preventive treatments.

13. The device described in the above-captioned application is a positive advance in the arsenal available to physicians and patients for cardiovascular preventative treatments.

Declarant further states that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: _4-14-02_   Name: _Herbert M. Dean_
Herbert M. Dean, M.D., F.A.C.P.

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HERBERT M. DEAN, M.D., F.A.C.P.
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Fallon Clinic

The Fallon Clinic is a multi specialty Group Practice in existence since 1929. I have been a member my entire professional career, beginning in 1968. I was the tenth physician in the group, currently there are over 300 physicians located in 33 sites throughout Worcester County.

Major Roles

Board Member of Fallon Clinic from inception of professional corporation in 1970 through February 1995.

Executive Vice President of the Board - 1988 - 1995

Director of Division of Hematology/Oncology (current)

Chairman of Fallon Clinic Pension Plan for the past 12 years, member since its inception.

Chairman of Performance Improvement Committee (PIC), a joint Fallon Clinic, Fallon Community Health Plan Committee. The PIC reports to both Boards as well as the State Board of Registration in Medicine and oversees quality management, utilization, credentialing, risk management and patient relations activities for both entities.

Chairman of the By-Laws Committee (1990)

Director of Fallon Clinic Laboratory, 1969 - 1991

Chairman of Fallon Clinic Pharmacy & Therapeutics Committee, 1982 - 1986

Member of Fallon Clinic and Fallon Community Health Plan Joint Planning Committee (Systems Planning Activity Group), 1986 - 1996

Fallon Community Health Plan

Fallon Community Health Plan is a not-for-profit federally qualified HMO with over 175,000 members including 25,000 members in our Senior Plans. Our Senior Plan was the first Medicare Risk Contract in the country and has been quite successful. Recently, FCHP received a full unconditional three year accreditation by the National Committee on Quality Assurance (NCQA).

Major Roles

President and CEO 1991 - present

Treasurer, FCHP 1988 - 1990

FCHP Board Member since 1986

Other System Positions

- ❖ Board Member of St. Vincent Healthcare System, St. Vincent Hospital, 1990 - present
- ❖ Board Member of Fallon Foundation
- ❖ Chairman, Medical Records, St. Vincent Hospital, 1970 - 1972
- ❖ Blood Bank, St. Vincent Hospital, 1970 - 1977
- ❖ Member of Executive Committee of Staff, St. Vincent Hospital, 1981 - 1983
- ❖ Quality Assurance Committee, St. Vincent Hospital, 1985 - 1987
- ❖ Nominating Committee, St. Vincent Hospital, 1989 - 1991
- ❖ Pharmacy & Therapeutics Committee, St. Vincent Hospital, 1985 - 1989
- ❖ Cancer Committee, St. Vincent Hospital, Current

Memberships

- ❖ Massachusetts Medical Society, 1968
- ❖ Worcester County Medical Society, 1968
- ❖ Massachusetts Society of Internal Medicine, 1970
- ❖ American Society of Hematology, 1970
- ❖ Fellow of American College of Physicians, 1970
- ❖ American Society of Clinical Oncology, 1973
- ❖ American College of Physician Executives, 1991

Education

College:	Columbia University, A.B., 1959
Medical School:	Tufts University, M.D., 1963
Internship:	Bellevue Hospital, Columbia Medical Division, 1963 - 1964
Residency:	Bellevue Hospital, Columbia Medical Division, 1964 - 1965
	Cleveland Metropolitan General Hospital, 1965 - 1966
	Chief Resident, Boston City Hospital; I and III Medical Services (Tufts), 1967 - 1968
Fellowship:	Tufts Hematology Laboratory, Boston City Hospital, 1966 - 1967 (Drs. Moloney and Desforges)
Medical Licensure:	Massachusetts

Medical Practice

Hematology/Oncology and Internal Medicine, Fallon Clinic, Inc. 1968 - Present

Hospital Appointments

❖ St. Vincent Hospital
❖ University of Massachusetts Medical Center

Board Certification

❖ Internal Medicine, October 1969
❖ Hematology, October, 1972
❖ Oncology, October, 1973

Professional Education Courses

American College of Physician Executives, Physicians in Management, Courses I, II, III - 1989, 1990, 1991

Harvard School of Public Health - Leadership Training in Managing Ambulatory Care for the Future, November, 1992

Group Health Association of America, Trends in Ambulatory Medicine, February, 1992

Publications

American Journal of Medicine. February, 1968, "The Relation of Hyperlipemia to Hemolytic Anemia in an Alcoholic Patient".

Annals of Internal Medicine, June, 1967, "Fatal Infection With Aeromonas Hydrophilia in a Patient with Acute Myelogenous Leukemia".

New England Journal of Medicine, September, 1967, "Temporary Survival With No Circulating Red Cells Secondary to Clostridial Hemolysis".

New England Journal of Medicine, October, 1968, "Acanthocytes After Splenectomy", Letter to Editor

Transfusion, July - August, 1979, "Measurement of Erythrocyte Survival During Open Heart Surgery"

Annals of Internal Medicine, November, 1990, "Annual Pelvic Examinations", Letter to Editor

New England Journal of Medicine, October, 1991, "The Effect of Unproved Cancer Therapy in Advanced Cancer, Letter to Editor

Teaching Appointments

Teaching Assistant, Tufts Medical School, 1966 - 1967

Teaching Fellow, Tufts Medical School, 1967 - 1968

Associate in Medicine, University of Massachusetts Medical School, 1973 - 1977

Assistant Professor of Medicine, University of Massachusetts Medical School, 1978 - Present

Miscellaneous Information

Born: New London, Connecticut, February 7, 1938

Marital Status: Married, Joan B. Podrat, 1963; two children

Exhbit B

Use of Aspirin, β-Blockers, and Lipid-Lowering Medications Before Recurrent Acute Myocardial Infarction

Missed Opportunities for Prevention?

Danny McCormick, MD, MPH; Jerry H. Gurwitz, MD; Darleen Lessard, MS; Jorge Yarzebski, MD, MPH; Joel M. Gore, MD; Robert J. Goldberg, PhD

Background: For patients who have had a previous myocardial infarction (MI), the use of aspirin, β-blockers, and lipid-lowering agents reduces the risk of recurrent MI and death.

Objective: To examine trends in and determinants of receipt of these 3 medications before hospitalization for recurrent acute MI (AMI).

Methods: The study population consisted of 1710 patients with a previous history of MI hospitalized with a validated recurrent AMI in all hospitals in Worcester, Mass, during 1986, 1988, 1990, 1991, 1993, and 1995. Logistic regression analyses were used to assess the effect of demographic, clinical, and temporal factors on the receipt of aspirin, β-blockers, and lipid-lowering medications before hospital admission for recurrent AMI.

Results: More than 47% of patients in each study year were not receiving each medication before admission, although significant increases in use were noted over time for aspirin (from 13.5% to 52.6%), β-blockers (from 33.2% to 44.4%), and lipid-lowering medications (from 0.8%

to 11.7%). In multivariate analyses, advancing age was associated with not receiving aspirin (odds ratio [OR], 0.67; 95% confidence interval [CI], 0.51-0.89), lipid-lowering medications (OR, 0.14; 95% CI, 0.08-0.25), and β-blockers (OR, 0.75; 95% CI, 0.57-1.00), although this effect was of borderline significance for β-blockers. Being a woman was associated with not receiving aspirin (OR, 0.78; 95% CI, 0.62-0.98) but was positively associated with receiving lipid-lowering medications (OR, 1.59; 95% CI, 1.04-2.43). Coexisting medical conditions and concurrent use of other cardiovascular medications were also associated with receipt of each medication.

Conclusion: Despite encouraging increases over time, the low absolute levels of receipt of medications shown to be efficacious in the long-term treatment of patients after an MI, and their variation by age and sex, suggest that substantial opportunities may exist to prevent recurrent AMIs through the increased use of aspirin, β-blockers, and lipid-lowering medications.

Arch Intern Med. 1999;159:561-567

From the Section for Health Services Research, Divisions of General Medicine/Primary Care/Geriatrics (Drs McCormick, Gurwitz, Yarzebski, and Goldberg) and Cardiovascular Medicine (Ms Lessard and Drs Yarzebski, Gore, and Goldberg), and the Meyers Primary Care Institute (Drs McCormick, Gurwitz, and Goldberg), University of Massachusetts Medical Center and the Fallon Healthcare System, Worcester.

MORTALITY associated with a recurrent acute myocardial infarction (AMI) is appreciably higher than that associated with a first AMI. Several medications exist, however, that have been shown to reduce the likelihood of recurrent AMI and death in patients who have established coronary artery disease, including patients who have had an initial AMI. The effectiveness of therapy with aspirin,[1-3] β-blockers,[3-9] and lipid-lowering medications[10-12] in the secondary prevention of AMI has been well established in large, randomized clinical trials and/or meta-analyses of the published literature. It has been estimated that use of these medications can reduce the risk of cardiovascular death and nonfatal reinfarction, respectively, by 22% and 27% for β-blockers,[3-8] 13% and 31% for aspirin,[3] and

14% and 25% for all lipid-lowering medications combined.[13] Based on this evidence, widely publicized guidelines strongly recommend the routine long-term use of aspirin and β-blockers[14,15] in patients who recently had an AMI and lipid-lowering medications in patients with elevated cholesterol levels following hospital discharge after AMI.[13,16]

Despite the positive findings of studies examining the effectiveness of these therapies and the widespread dissemination of these practice guidelines, findings of several previous studies[17-23] suggest that these medications are underprescribed to patients at hospital discharge after an AMI. Results of previous studies also suggest that nonclinical factors such as age,[17,21] sex,[20] and type of medical insurance[20] may affect the likelihood of receiving these medications at hospital discharge after an AMI.

PATIENTS AND METHODS

This investigation was conducted as part of the Worcester Heart Attack Study, a multihospital, population-based investigation of time trends in the attack and survival rates associated with AMI.[24-28]

STUDY POPULATION

The population studied consisted of patients hospitalized with a primary or secondary diagnosis of AMI (*International Classification of Diseases*, Ninth Revision, code 410)[9] in all acute care general hospitals in the Worcester (Mass) Standard Metropolitan Statistical Area (1990 census estimate = 437 000) during 1986, 1988, 1990, 1991, 1993, and 1995, who had a history of myocardial infarction (MI). Sixteen university-affiliated and community hospitals were originally included in this study, with fewer hospitals included in recent study years because of hospital closures or conversions to long-term care facilities. The medical records of greater Worcester residents with a discharge diagnosis of AMI from these hospitals were individually reviewed and validated according to pre-established diagnostic criteria that have been described previously.[10-12] In brief, these criteria included a clinical history of prolonged chest pain not relieved by nitrate therapy or rest; increased total and isoenzyme subfractions of creatine kinase or lactate dehydrogenase; and serial electrocardiographic findings of ST segment changes or Q waves typical of AMI. At least 2 of these 3 criteria needed to be satisfied for study inclusion. Presence of a previous history of MI was assessed through information provided by the patient that was documented in the medical record at hospital admission and confirmed through review of the medical record of previous hospitalization for AMI at areawide hospitals.

DATA COLLECTION

The hospital records of patients with validated AMI were abstracted for demographic (age, sex, and race) and clinical data (medical history of previous MI, angina, hypertension, diabetes, congestive heart failure, or stroke), type of medical insurance, total serum cholesterol level observed during hospitalization, and preadmission medication use (aspirin, β-blockers, lipid-lowering medications, calcium channel blockers, diuretics, warfarin sodium, antiarrhythmic medications, and digoxin). Patients were considered to be taking a medication before admission if it was listed as a current outpatient medication in the medical record on the day of hospital admission for recurrent AMI. This information was provided by patients themselves, their usual outpatient physicians, or other referring institutions, such as long-term care facilities. Outpatient medical records were not used for verification of medical regimens.

STATISTICAL ANALYSIS

Time trends in the use of aspirin, β-blockers, and lipid-lowering medications before hospitalization for recurrent AMI were analyzed by determining the percentages of patients who received each of these medications by study year. A 2-sided Cochran-Armitage test for trend was used to determine statistical significance.

Demographic and clinical correlates of receiving each medication were evaluated for the study sample (all study years combined), and relative risks and 95% confidence intervals (CIs) were calculated for each variable. These variables were used to develop separate stepwise multivariate logistic regression models with use of aspirin, β-blockers, and lipid-lowering medication as the outcome variables. Candidate variables in these analyses included race (white vs all other races), medical history (angina, hypertension, diabetes, congestive heart failure, and stroke), concurrent (preadmission) use of other medications (aspirin, β-blockers, lipid-lowering medications, calcium channel blockers, diuretics, warfarin, antiarrhythmic medications, and digoxin), medical insurance (private vs Medicare, Medicaid, and uninsured), and total serum cholesterol level observed in the hospital (≥ 5.17 vs < 5.17 mmol/L [≥ 200 vs < 200 mg/dL]). Complete lipid profile laboratory data were not available for study participants. Our definition of a high serum cholesterol level (total cholesterol level ≥ 5.17 mmol/L [≥ 200 mg/dL]) was used to serve as a proxy for a low-density lipoprotein cholesterol level of approximately 3.36 mmol/L or greater (≥ 130 mg/dL),[10] the level at which medical treatment of hypercholesterolemia in patients with established coronary heart disease is recommended by the National Cholesterol Education Project guidelines, published in 1994.[13] Variables were dropped from each model at a significance level of $P < .05$. Because of a priori importance, age (< 65, 65-74, and ≥ 75 years), sex, and study year (with 1995 as the referent category) were forced into all models. For each model, we reported adjusted odds ratios (ORs) and 95% CIs for all variables.

However, among patients experiencing recurrent AMI, little is currently known about the use of these medications before the event. Patients who have had a previous AMI are at particularly high risk for recurrent AMI and death; patients who have recurrent AMI and are not using these medications may thus represent missed opportunities for prevention. Understanding the factors associated with receipt of these medications for patients with recurrent AMI may help to overcome obstacles to optimizing their use.

The objectives of this observational, community-wide study were (1) to examine trends over time in the percentages of patients receiving aspirin, β-blockers, and lipid-lowering medications at hospital admission for recurrent AMI and (2) to identify factors that are associated with the receipt of these agents in patients with previous AMI.

RESULTS

PATIENT CHARACTERISTICS

The total study population comprised 1710 patients, most of whom were older than 65 years, male, and white, with no private medical insurance (**Table 1**). Coexisting medical conditions were common: 43.0% had angina, 58.1% had hypertension, 34.3% had diabetes, 31.2% had a history of congestive heart failure, and 36.2% had a total cho-

Table 1. Bivariate Analysis of the Association of Various Characteristics With the Race ... β-Blockers, Aspirin, and Lipid-Lowering Medications Before Hospital ...ssion for Recurrent Myocardial Infarction: Worcester Heart Attack Study, 1986-1995

Characteristics	Patients, No. (%)	Risk Ratio (95% Confidence Interval)*		
		For Receiving Aspirin	For Receiving β-Blockers	For Receiving Lipid-Lowering Medications
Demographics				
Age, y				
<65	475 (27.8)	(Referent)		
65-74	476 (27.8)	0.93 (0.79-1.08)	(Referent)	(Referent)
≥75	759 (44.4)	0.81 (0.70-0.94)	0.97 (0.83-1.13)	0.71 (0.49-1.03)
Women	685 (40.0)	0.86 (0.76-0.98)	0.81 (0.70-0.94)	0.23 (0.14-0.38)
White	1593 (93.2)	1.09 (0.84-1.41)	0.96 (0.85-1.09)	0.93 (0.55-1.31)
Private insurance	552 (32.3)	1.02 (0.89-1.16)	0.76 (0.63-0.93)	1.43 (0.64-3.18)
Medical history			1.02 (0.89-1.16)	1.57 (1.18-2.35)
Angina	735 (43.0)	1.24 (1.10-1.40)	1.41 (1.25-1.60)	1.11 (0.79-1.56)
Hypertension	993 (58.1)	1.12 (0.99-1.27)	1.56 (1.36-1.78)	1.17 (0.82-1.56)
Diabetes	586 (34.3)	1.11 (0.98-1.26)	1.10 (0.97-1.25)	1.03 (0.72-1.47)
Congestive heart failure	554 (31.2)	0.97 (0.85-1.11)	0.80 (0.70-0.93)	0.77 (0.53-1.14)
Stroke	219 (12.8)	1.23 (1.04-1.45)	1.03 (0.86-1.24)	0.95 (0.56-1.59)
Cholesterol level, mmol/L (mg/dL):				
<5.17 (<200)	1091 (63.8)	(Referent)	(Referent)	(Referent)
5.17-6.18 (200-239)	313 (18.3)	1.10 (0.94-1.29)	1.07 (0.91-1.26)	1.54 (1.02-2.32)
≥6.21 (≥240)	306 (17.9)	0.98 (0.83-1.16)	1.12 (0.95-1.31)	1.01 (0.84-2.04)
Medication use on admission				
Aspirin	635 (37.1)		1.54 (1.46-1.86)	3.79 (2.82-5.48)
β-Blockers	637 (37.3)	1.55 (1.46-1.86)	...	2.02 (1.43-2.93)
Lipid-lowering medications	123 (7.2)	1.99 (1.74-2.29)	1.52 (1.27-1.81)	...
Calcium channel blockers	751 (43.9)	1.21 (1.07-1.37)	1.10 (0.97-1.25)	1.34 (0.95-1.89)
Diuretics	665 (38.9)	0.88 (0.77-1.00)	0.83 (0.72-0.95)	0.85 (0.59-1.21)
Warfarin	133 (7.8)	0.84 (0.65-1.09)	1.23 (1.01-1.50)	1.28 (0.73-2.26)
Antiarrhythmic medications	166 (9.7)	1.15 (0.95-1.39)	2.01 (1.77-2.27)	1.39 (0.84-2.29)
Digoxin	435 (25.4)	1.00 (0.86-1.16)	0.72 (0.61-0.85)	0.75 (0.49-1.14)

*Ellipses indicate not applicable.

lesterol level greater than 5.17 mmol/L [>200 mg/dL]. The percentages of patients receiving aspirin, β-blockers, and lipid-lowering medications at hospital admission were 37.1%, 37.3%, and 7.2%, respectively. Concurrent use of additional cardiovascular medications varied, ranging from 43.9% of patients taking a calcium channel blocker to 7.8% of patients taking warfarin.

RECEIPT OF ASPIRIN, β-BLOCKERS, AND LIPID-LOWERING MEDICATIONS BEFORE ADMISSION FOR RECURRENT AMI

Aspirin

The percentages of patients with AMI who were receiving aspirin at hospital admission increased significantly ($P<.001$) during the 5 study years, from 13.5% in 1986 to 32.6% in 1995 (**Figure 1**). Older patients and women were significantly less likely to be receiving aspirin, whereas patients who had a history of angina or stroke or who were concurrently receiving β-blockers, lipid-lowering medications, or calcium channel blockers were more likely to be receiving aspirin (Table 1).

In the multivariate regression model, 10 demographic and clinical variables were identified as having an independent association with receiving aspirin at hospital admission (**Table 2**). Enrollment in earlier study years (compared with more recent study years) was associated with
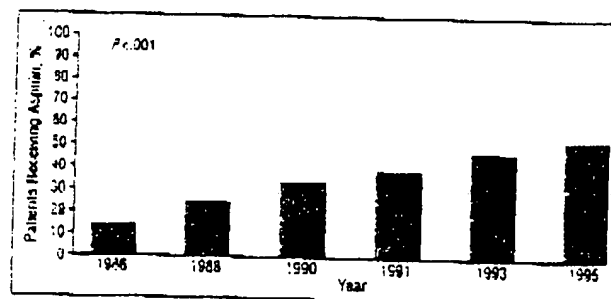

Figure 1. Temporal trends in the receipt of aspirin before hospital admission for recurrent acute myocardial infarction: Worcester Heart Attack Study 1986-1995.

not receiving aspirin (OR, 0.13; 95% CI, 0.09-0.21; comparing 1986 with 1995). Advancing patient age (OR, 0.67; 95% CI, 0.51-0.89; for age >75 years compared with age <65 years) and female sex (OR, 0.78; 95% CI, 0.62-0.98) were also associated with not receiving aspirin. As in the bivariate analysis, history of angina or stroke and concurrent use of several other cardiovascular medications, including β-blockers and lipid-lowering medications, were associated with receiving aspirin.

β-Blockers

The percentages of patients with AMI who were receiving β-blockers at hospital admission increased mod-

Table 2. Variables Predicting Receipt of Aspirin Before Admission for Recurrent Acute Myocardial Infarction: Worcester Heart Attack Study

Variable	Adjusted Odds Ratio (95% Confidence Interval)
Age, y	
<65	1.00 (Referent)
65-74	0.84 (0.84-1.11)
≥75	0.67 (0.51-0.88)
Women	0.78 (0.62-0.98)
Study year	
1995	1.00 (Referent)
1993	0.81 (0.59-1.10)
1991	0.58 (0.41-0.81)
1990	0.44 (0.31-0.63)
1988	0.29 (0.19-0.43)
1986	0.13 (0.09-0.21)
History of angina	1.30 (1.04-1.63)
History of stroke	1.41 (1.02-1.93)
Concurrent β-blocker use	2.14 (1.71-2.67)
Concurrent lipid-lowering drug use	2.61 (1.70-4.00)
Concurrent calcium channel blocker use	1.39 (1.12-1.74)
Concurrent warfarin use	0.45 (0.29-0.68)
Concurrent digoxin use	1.44 (1.12-1.87)

Table 3. Variables Predicting Receipt of β-Blockers Before Admission for Recurrent Acute Myocardial Infarction: Worcester Heart Attack Study

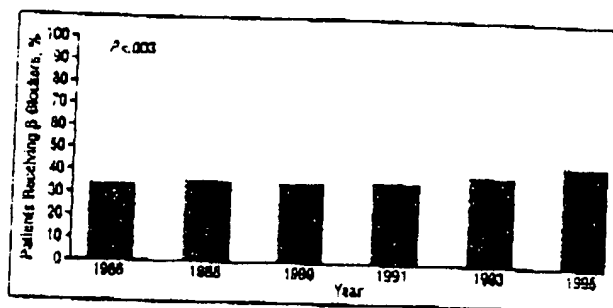| Variable	Adjusted Odds Ratio (95% Confidence Interval)
Age, y	
<65	1.00 (Referent)
65-74	1.02 (0.78-1.35)
≥75	0.75 (0.57-1.00)
Women	1.05 (0.83-1.32)
White	0.53 (0.35-0.72)
Study year	
1995	1.00 (Referent)
1993	0.75 (0.54-1.05)
1991	0.63 (0.43-0.91)
1990	0.62 (0.42-0.90)
1988	0.83 (0.56-1.24)
1986	0.92 (0.63-1.36)
History of angina	1.73 (1.39-2.14)
History of hypertension	2.19 (1.75-2.76)
Total cholesterol level >5.17 mmol/L (>200 mg/dL)	1.30 (1.03-1.64)
Concurrent aspirin use	2.22 (1.76-2.78)
Concurrent warfarin use	1.72 (1.14-2.60)
Concurrent diuretic use	0.70 (0.55-0.89)
Concurrent antiarrythmic medication use	5.25 (3.60-7.86)
Concurrent digoxin use	0.57 (0.43-0.76)

Figure 2. *Temporal trends in the receipt of β-blockers before hospital admission for recurrent acute myocardial infarction: Worcester Heart Attack Study, 1986-1995.*
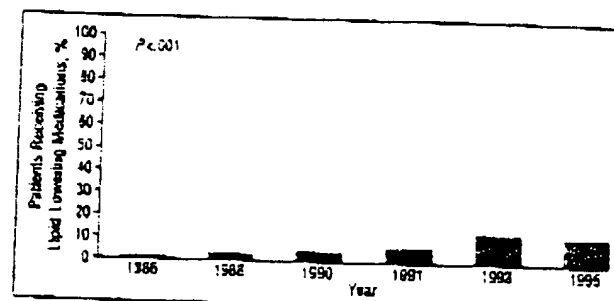

Figure 3. *Temporal trends in the receipt of lipid-lowering medications before hospital admission for recurrent acute myocardial infarction: Worcester Heart Attack Study, 1986-1995.*

estly (P<.003) during the 6 study years, from 33.2% in 1986 to 44.4% in 1995 (**Figure 2**). Advancing age, white race, a history of congestive heart failure, and use of diuretics or digoxin were associated with not receiving a β-blocker (Table 1). Patients with a history of angina or hypertension or who were concurrently receiving aspirin, lipid-lowering medications, warfarin, or antiarrhythmic medications were more likely to receive a β-blocker.

In the multivariate regression model, 12 demographic and clinical variables were identified as having an independent association with receiving a β-blocker (**Table 3**). Although there was a statistically significant increase in the odds of receiving a β-blocker from 1990 (OR, 0.62; 95% CI, 0.42-0.90) and 1991 (OR, 0.63; 95% CI, 0.43-0.91) to 1995, the odds of receiving this medication in earlier years (1986 or 1988) were no lower than in the most recent study year (1995). As in the bivariate analysis, advancing patient age (OR, 0.75; 95% CI, 0.57-1.00) and white race (OR, 0.53; 95% CI, 0.35-0.72) were associated with not receiving a β-blocker. History of angina or hypertension and concurrent use of other cardiovascular medications, including aspirin and lipid-

lowering medications, were again positively associated with receiving a β-blocker.

Lipid-Lowering Medications

The percentages of patients with AMI who were receiving lipid-lowering medications increased significantly (P<.001) during the 6 study years, from 0.8% in 1986 to 11.7% in 1995 (**Figure 3**). Older patients, women, and those not covered by private medical insurance were significantly less likely to be receiving a lipid-lowering medication, whereas patients who had an elevated cholesterol level (≥5.17 mmol/L [≥200 mg/dL]) or who were concurrently receiving β-blockers or aspirin were more likely to be receiving a lipid-lowering medication (Table 1). This low level of receipt of lipid-lowering medications was despite the finding that more than 36.2% of patients had a total cholesterol level greater than 5.17 mmol/L (>200 mg/dL) (Table 1).

Table 4. Variables Predicting Receipt of Lipid-Lowering Medications Before Admission for Recurrent Acute Myocardial Infarction: Worcester Heart Attack Study

Variable	Adjusted Odds Ratio (95% Confidence Interval)
Age, y	
<85	1.00 (Referent)
85-74	0.60 (0.39-0.93)
≥75	0.14 (0.08-0.25)
Women	1.59 (1.04-2.43)
Study year	
1995	1.00 (Referent)
1993	1.11 (0.68-1.80)
1991	0.44 (0.23-0.84)
1990	0.29 (0.14-0.60)
1988	0.16 (0.06-0.44)
1986	0.07 (0.02-0.30)
Total cholesterol level >5.17 mmol/L (>200 mg/dL)	1.77 (1.16-2.69)
Concurrent aspirin use	2.86 (1.98-4.32)
Concurrent calcium channel blocker use	1.53 (1.03-2.27)

In the multivariate regression model, 6 demographic and clinical variables were identified as having an independent association with receiving a lipid-lowering medication (**Table 4**). Enrollment in earlier study years was associated with not receiving a lipid-lowering medication. Advancing patient age (OR, 0.14; 95% CI, 0.08-0.25) also remained associated with not receiving a lipid-lowering medication. An elevated serum cholesterol level and concurrent use of other cardiovascular medications were, as in the bivariate analysis, also associated with receipt of a lipid-lowering medication. In contrast to the bivariate analysis, women were significantly more likely to be receiving a lipid-lowering medication after controlling for demographic and clinical factors.

COMMENT

Evidence-based clinical guidelines strongly endorse the use of aspirin and β-blockers in nearly all patients who have experienced an MI and do not have specific contraindications[14,15] and the use of lipid-lowering medications in those with elevated serum cholesterol levels.[13,16] Studies establishing the efficacy of using these medications for secondary prevention in coronary heart disease, on which these practice guidelines are based, were published before the first year of the present investigation. Despite widespread dissemination of this information, we found that, even by 1995, more than half of all patients who were first seen with recurrent AMI were not receiving aspirin or a β-blocker and that most patients (>90%; two thirds of those with an elevated cholesterol level) were not receiving a lipid-lowering medication. Although receipt of aspirin and lipid-lowering medications increased substantially during the approximately 10-year study, only modest changes were noted for β-blocker use. In addition to comorbidities and concurrent cardiovascular medication use, receipt of these medications was significantly affected by nonclinical factors such as age and sex. These findings suggest substantial

missed opportunities for the prevention of recurrent AMI with the use of these effective therapies.

Results of well-designed clinical trials have been shown to affect the prescription of cardiovascular medications by physicians.[30,33] However, results of several previous studies conducted in the 1990s found significant underuse of aspirin[17,19] and β-blockers[18,20-23] at hospital discharge after an initial AMI despite the demonstrated efficacy of these medications in published clinical trials. Undertreatment of hypercholesterolemia among patients with established coronary heart disease also has been previously described.[34] The low rates of prescribing these medications have been attributed to deficits in physician knowledge of medication effectiveness because of long delays in the dissemination of the results of clinical research to practicing clinicians.[22,34-38] For example, results of a recent study[38] show that the time lag between published meta-analyses that established the efficacy of using aspirin and β-blockers in the secondary prevention of MI and the recommended use of these medications by more than half the authors of review articles and textbook chapters on the subject was 6 and 2 years, respectively. In addition, despite the publication of evidence-based practice guidelines recommending treatment of hypercholesterolemia for patients with established coronary heart disease in 1988,[16] the use of lipid-lowering medications was not yet recommended by more than half the authors of review articles and textbook chapters on the subject 2 years later.[38] This considerable time lag between the publication of results of clinical trials and the acquisition of this knowledge by physicians may be largely responsible for the low percentages of patients receiving aspirin, β-blockers, and lipid-lowering medications that we observed and the dramatic increases in receipt of aspirin and lipid-lowering medications years after their effectiveness was first demonstrated.

We also found that, although aspirin, β-blockers, and lipid-lowering medications were received by relatively small percentages of patients after an MI, these medications were received at even lower levels by several clinically and demographically defined patient subgroups. As expected, patients with cardiovascular risk factors and comorbid conditions tended to be more likely to be receiving any one of the 3 medications of interest, and patients who were currently using any 1 of these medications were more likely to be using another of them. However, nonclinical factors such as age and sex also affected patterns of receipt of these medications. Patients who were older (≥75 years) were significantly less likely to use any of the 3 medications, a finding consistent with previous studies that show underuse of β-blockers[20-22] and aspirin[17] in elderly patients at hospital discharge after AMI. Yet, the survival benefit from β-blocker[21,39] and aspirin[1] therapy in patients with established coronary heart disease appears to be at least as great for elderly as nonelderly patients. The benefits of therapy with lipid-lowering medications in elderly patients with established coronary heart disease have not been clearly demonstrated because most large clinical trials do not include adequate numbers of elderly patients. Nonetheless, because there is no evidence that the basic pathophysiological processes underlying coronary atherogenesis

are different for elderly and nonelderly patients. National Cholesterol Education Program guidelines recommend that age alone should not be a reason to treat hypercholesterolemia less aggressively.[13]

Women in the present population-based study were significantly less likely to be receiving aspirin at the time of reinfarction, a finding consistent with that of a previous study[10] showing that aspirin is used less often for women than for men after an initial MI. As with increasing age, results of previous research do not suggest a less beneficial effect of aspirin use in women than in men with previous MI.[1] However, in our multivariate models, being a woman was associated with greater odds of receiving a lipid-lowering agent. Thus, patient sex seems to have a variable effect on the odds of receiving effective therapies at the time of recurrent AMI.

Lack of physician awareness of the results of clinical trials demonstrating the effectiveness of these medications or of practice guidelines recommending the use of these medications irrespective of age or sex may contribute to the low percentages of patients receiving these medications that we observed. It is also likely that use of these 3 medications was affected by the presence of clinical contraindications. β-blocker use is contraindicated in patients with heart block, bradycardia, congestive heart failure, reactive airways disease, diabetes mellitus, and depression, and aspirin use may be contraindicated in patients with bleeding disorders, peptic ulcer disease, thrombocytopenia, and aspirin allergy. Use of lipid-lowering medications is contraindicated in few patients. Because data were only available for a few coexisting illnesses that could constitute a contraindication to medication use, we could not assess the magnitude of the impact of clinical contraindications on the rates of use of these medications. However, of patients screened for possible inclusion in the largest β-blocker trials, the proportion who had contraindications to β-blocker use did not exceed 18%.[7,41] In a previous aspirin trial,[42] the percentage of screened patients who were excluded because of contraindications to aspirin use was less than 4%. Although it is possible that patients with recurrent AMI may have more contraindications to medication use than patients in these clinical trials, it seems unlikely that such differences could completely account for the low medication use rate that we observed.

Beyond physician prescribing practices, the patient's inability to comply with physician recommendations may contribute to lower use rates. It is possible that the cost of long-term therapy may discourage some patients from continuing to use these medications. We found that patients with private insurance were more likely to be using lipid-lowering medications, most classes of which are relatively expensive (eg, 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors), at the time of their recurrent MI. This relationship did not persist in the multivariate model, but it is possible that this was caused by either low statistical power because of the small number of patients using lipid-lowering medications or residual confounding by age because patients with nonprivate insurance (including Medicare) were more likely to be older. The relationship between insurance status and use of lipid-lowering medications in patients after an MI, therefore, deserves further study. For use of β-blockers and aspi-

rin, 2 relatively inexpensive medications, we found no association with medical insurance status.

It is also likely that patients' inability to tolerate the adverse effects of these medications contributed to the low usage rates we observed. In a previous large study[44] of patients who have experienced an MI, the Beta-blocker Heart Attack Trial, withdrawal of β-blocker therapy because of adverse effects was 13% for 2 years of follow-up. In the Coronary Drug Project Research Group trial[43] of aspirin for secondary prevention, only 4.5% of patients taking aspirin were compliant with therapy less than 20% of the time during an average of 22 months of follow-up. However, results of a previous study[48] show that rates of discontinuation of lipid-lowering medication use in the primary care setting (primary and secondary prevention patients combined) were variable, depending on the particular agent prescribed, and were higher, in general, than the rates reported in clinical trials. Unfortunately, no data were collected as part of our study that would allow us to assess the impact of this problem on receipt of medications examined in this study.

Although it is likely that each factor discussed has some effect on the rate of use of these medications, physician prescribing behavior is likely to have the greatest impact. Results of previous studies on receipt of aspirin and β-blockers by patients after an MI indicate that physicians do not prescribe these medications to 15% to 25% of eligible patients at hospital discharge. Furthermore, the rapid rise in the use of aspirin and lipid-lowering medications over time in the present study more likely reflects substantial changes in physician prescribing behavior because of the acquisition of new knowledge about health benefits associated with these agents rather than dramatic changes in the prevalence of contraindications to using these medicines or changes in patients' ability to comply with recommended therapy.

Residents of the Worcester metropolitan area are similar to those of the overall United States with respect to characteristics such as age, sex, and socioeconomic status but not for race.[14,30] By including all patients hospitalized with recurrent AMI from a defined geographic area, this study minimized the likelihood of selection biases that may be present in studies of patients hospitalized in single or referral hospitals. Several limitations of this study should also be noted. First, to assess medication use just before admission, we relied on documentation of the patient's outpatient medical regimen in the medical record at hospital admission for recurrent AMI. To the extent that this information in many cases came from patient self-report, inaccuracies in patient recall could have led to some underestimates or overestimates of the rates of use of these medications.

Second, although detailed information about cardiovascular comorbidities and concurrent medication use was available for study patients, information on the complete range of additional comorbidities that could represent absolute or relative contraindications to use of the 3 medications examined was not available. In addition, information about discontinuation of medication use because of adverse effects was not known. Thus, we could not determine the "right" percentage of patients who should have been receiving each medication we examined. Third, although this study highlights the small percentages of patients receiving these medications in ac-

al practice, we were not able to assess the reasons underlying these patterns of care. Future studies will need to address the relative impact of physicians' failure to prescribe these medications and patients' inability or choice not to comply with recommended therapies.

In summary, this study documents the extent of underuse of aspirin, β-blockers, and lipid-lowering medications by patients with a previous history of MI who later experience a recurrent AMI and identifies clinical and non-clinical factors associated with this underuse. Although the rates of use of the cardiovascular medications we studied may be higher for patients after an MI who did not have a recurrent event (to the extent that these medications are effective), our findings confirm that there remain substantial missed opportunities to treat patients after an MI with medications that are shown to reduce the risk of recurrent MI and cardiovascular death. Given the high prevalence of MI, concerted efforts should be undertaken to facilitate more rapid transmission of the results of clinical trials of cardiovascular medications to practicing physicians and to reduce substantial variation in treatment practices that seems to be related to patient age and sex.

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EXHIBIT C

HEDIS 2000 Narrative

What's in It and Why It Matters

NCQA

Measuring the Quality of America's Health Care

the visit, and then mailed back with results. Other MCOs send reminder "birthday" cards encouraging women to receive recommended Pap tests. Allowing an annual OB/GYN visit without a referral also removes one potential barrier to cervical cancer screening, and may help boost screening rates.

Prenatal Care in the First Trimester

This measure looks at how well our delivery system works for newly pregnant women. It estimates the percentage of pregnant women in the MCO who began prenatal care during the first 13 weeks of pregnancy. Care can be delivered by a variety of appropriate obstetrical, primary care or nurse midwifery providers.

The concept of prenatal care is a prototype of preventive medicine. Healthy diet counseling, vitamin supplementation, identification of maternal risk factors and health promotion all need to occur early in pregnancy to have a maximum impact on outcomes. Poor outcomes include spontaneous abortions, low birthweight babies, large for gestational age babies, neonatal infections and countless others.

Early prenatal care is also an essential part of what is needed to help a pregnant woman prepare to become a mother.

Nationally, 10 percent of MCOs had rates for prenatal care in first trimester of 95.1 percent or greater, as of 1998. If the rest of MCOs performed at this level, preventable loss of life and illness could be avoided.

What can MCOs do to improve rates of prenatal care in first trimester? MCOs and providers should develop comprehensive exercise and educational programs for pregnant women focusing on the importance and benefits of prenatal care for both mothers and infants and about the significant risks associated with drug or alcohol use during pregnancy. MCOs should also consider developing incentive programs to encourage broader participation in such programs. Assigning case managers to high-risk members may also help encourage appropriate prenatal care and decrease dangerous behaviors.

Check-Ups After Delivery

This measure looks at the care rendered to women after they have a delivered a baby. It estimates the percentage of women who had live births who had a postpartum visit between 21 days and 56 days after delivery.

The eight weeks after giving birth are a period of physical, emotional and social changes for the mother, during a time when she is also adjusting to caring for her new baby.

In order to give clinicians that care for new mothers the chance to offer advice and assistance, the American College of Obstetricians and Gynecologists recommends that women see their health care provider at least once between 4 and 6 weeks after giving birth. The first postpartum visit should include a physical examination, and an opportunity for the health care provider to answer parents' questions and give family planning guidance and counseling on nutrition.

Beta Blocker Treatment After a Heart Attack

This measure looks at one way of preventing a second heart attack. It estimates the number of MCO members who were discharged from the hospital, after surviving a heart attack, who received a prescription for a type of drug called a beta blocker. Excluded are those who have a valid medical reason not to take the drug.

Heart disease is the leading cause of death in the U. S., and every year more than 500,000 Americans die from it. The American Heart Association estimates that the total annual cost of medical care and lost productivity due to heart disease is $12 billion to $24 billion. Annually, approximately 1.5 million Americans suffer a heart attack.

A heart attack occurs when the blood supply to part of the heart muscle is severely reduced or stopped and heart tissue is destroyed by a lack of oxygen.

People who have had a heart attack are at high risk of having another one. One medical therapy that has been shown to lower that risk is the use of beta blockers, which lower blood pressure and reduce how hard the heart has to work.

Nationally, 10 percent of MCOs had rates for beta blocker treatment after a heart attack of 93.1 percent or greater, as of 1998. If the rest of the MCOs performed at this level, more than 2,900 cardiac deaths would be avoided each year. The number of future heart attacks avoided would be even higher. Expenditures for cardiac care would also be reduced by tens of millions of dollars annually.

What can MCOs do to improve beta blocker treatment rates? Many physicians are unaware of the extent to which these drugs improve cardiac outcomes, and therefore fail to prescribe them when appropriate. The key to improving rates of use is for the MCO to educate providers about the value of these agents, provide incentives to encourage their use, and provide physicians with guidelines and other decision support tools that will assist them in prescribing drugs appropriately.

Cholesterol Management After Acute Cardiovascular Events

Each year, about 1.5 million people are diagnosed with coronary artery disease and almost half a million die from the disease. Coronary heart disease remains the single leading cause of death in America today.

This measure assesses two components of cholesterol management for persons who are known to have heart disease by virtue of having had an acute cardiovascular event within the prior year: the percentage of members who have an LDL-C screening and the percentage of members who have a documented LDL-C level below 130 mg/dL.

Total blood cholesterol is directly related to the development of coronary artery disease and coronary heart disease, with most of the risk associated with LDL cholesterol. When LDL-C levels are high, cholesterol can build up within the walls of the arteries causing atherosclerosis, the build-up of plaque. Hemorrhaging or clot formation can occur at the site of plaque build-ups, blocking arteries and causing heart attack and stroke.

Reducing cholesterol in patients with known heart disease is critically important, as treatment can reduce morbidity (heart attacks and strokes) and mortality by as much as 40 percent. The National Cholesterol Education Program, NCEP, has laid out guidelines for the management of cholesterol in patients with heart disease. These guidelines establish the need for close monitoring of LDL-cholesterol in patients with coronary heart disease, and set a target for low density lipoprotein cholesterol (LDL-C) of 100 mg/dL or less for such patients.*

NCQA supports the NCEP recommendation that the target for therapy in patients with coronary heart disease is an LDL-C less than or equal to 100 mg/dL. The HEDIS measure nonetheless sets the target at an LDL-C less than 130 mg/dL for two important reasons. First, several appropriate therapeutic options exist for further risk reduction in patients with LDL-C between 100 mg/dL and 130 mg/dL: not all of which are likely to bring LDL-C to below 100 mg/dL. Clinicians should not be penalized for selecting these options when they feel that they are most appropriate for their patients. Second, few patients with coronary heart disease are currently reaching NCEP goals; the measure as we have defined it is more likely to permit those MCOs that are successfully making progress toward these goals to be recognized

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* The NCEP guidelines—as well as other materials that may help managed care organizations improve the management of patients with high cholesterol—can be obtained from the National Heart, Lung, and Blood Institute Health Information Network: PO Box 30105, Bethesda, MD 20824-0105. Phone: 301-592-8573; Fax: 301-592-8563, E-mail: nhlbiinfo@rover.nhlbi.nih.gov